

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS PO Box 1450 Alcassedan, Virginia 22313-1450 www.emplo.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,557	03/28/2006	Nobutaka Fujii	8156/88040	1863
42798 FITCH, EVEN, TABIN & FLANNERY P. O. BOX 18415			EXAMINER	
			DAVIS, ZINNA NORTHINGTON	
WASHINGTON, DC 20036			ART UNIT	PAPER NUMBER
			1625	
			MAIL DATE	DELIVERY MODE
			04/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/564,557 FUJII ET AL. Office Action Summary Examiner Art Unit Zinna Northington Davis 1625 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-7 is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-7 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on 13 January 2006 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date 1/06; 07/06; 12/07.

Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Notice of Draftsperson's Patent Drawing Review (PTO-948)

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date. \_\_\_\_\_.

6) Other:

5) Notice of Informal Patent Application

Page 2

Application/Control Number: 10/564,557

Art Unit: 1625

## DETAILED ACTION

- 1. Claims 1-7 are pending.
- 2. The drawings filed January 13, 2006 have been accepted.
- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 3, the period should be at the end of the claim.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 1-6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kalish et al (Reference A. cited by Applicants).

Kalish et al. teach a class of pharmaceutical formulations which are useful for treating HIV infection and AIDS. See page 1. At page 3, the generic formula is disclosed as follows:

Application/Control Number: 10/564,557

Art Unit: 1625

wherein:

- Q<sub>1</sub> and Q<sub>2</sub> are independently selected from hydrogen and substituted and unsubstituted alkyl and aryl, and Q<sub>2</sub> and Q<sub>3</sub> may form a ring with G<sub>4</sub>.
- Q<sub>s</sub> is selected from mercapto and substituted and unsubstituted allowyl, arylwsyl, thioether, amino, alkyl, cyclonikyl, saturated and partially saturated beteracycle, and aryl.
- Q<sub>n</sub>=Q<sub>n</sub> are independently selected from hydrogen, hydroxyl, nerespo, nitre, halogen, ———, wherein I is a substituted or unsubtituted hydroxynile group, and subshized and unsubstituted alkoxyl, surjoxyl, throe-ther, acyl, suffaryl, selfonyl, sunine, sillyl, evolutilely, sharmard and perintly sustained heterocylestically, sharmard heterocylestically as the surject of the company of the com

E is carbon or introgen,

- Q<sub>ii</sub> is selected from hydrogen, halogen, hydroxyl, morcapin, and substituted and unsubstituted alkoxyl, aryloxyl, thorather, minor, alkyl, and aryl, wherein Q<sub>i</sub> may form part of a ring.
- A is a carbacycle or beienwycle, which is optionally further substituted,
- and B is a carbocycle or heterocycle, which is optionally further substituted.

or a phermsocutically acceptable valutheroof.

At page 17, lines 35-45, the following species is taught. See the compound depicted below:

and

at page 20, lines 30-40, the following species is taught. See the compound depicted below:

Page 4

Application/Control Number: 10/564,557

Art Unit: 1625

The claims are fully met when R1 is arvl, m is 1; and Y is S; R1 is arvl and m is O.

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
  obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over
   Kalish et al (Reference A1, cited by Applicants) in view of Cinatl et al. (Reference C1, cited by Applicants).

Kalish et al. teach a class of HIV protease inhibitors. At page 3, the generic formula is disclosed as follows:

Art Unit: 1625

wherein:

- Q, and Q<sub>2</sub> are independently selected from hydrogen and substituted and unsubstituted alkyl and aryl, and Q<sub>2</sub> and Q<sub>2</sub> may form a ring with G,
- $Q_{\rm a}$  is solveted from mercapto and substituted and unsubstituted allowyl, arykeys, thioether, amino, alkyl, eyelvalkyl, saturated and partially saturated interacycle, and aryl,
- Q<sub>x</sub>=Q<sub>x</sub> are independently selected from hydrogen, hydroxyl, nexcapo, nitro, halogen, —0—I, wherein I is a substituted or mushathured hydrolyzable group, and substituted and transhathured alloxyl, surjoxyl, time-ther, acyl, suffinyl, suffonyl, amino, sllyl, cycloxicly, startnessed and pornishly sustanted heteroterior and the surface of the surface of the conmay's a member of a spiro ring and any two of Ω<sub>x</sub>=Q<sub>x</sub> may be a member of a spiro ring and any two of Ω<sub>x</sub>=Q<sub>x</sub>.
- Y and G are independently sciented from oxygen, ....NH, ....N-alkyl, sather, setenium, and two hydrogen atoms, II is carbon or nitrogen.

E is earbon or mitrogen,

- U<sub>n</sub> is selected from hydrogen, halogen, hydroxyl, morcapie, and substituted and unsubstituted alkoxyl, aryloxyl, this miner, amon, alkyl, and aryl, wherein Q<sub>n</sub> may from part of a ring.
- A is a carbocycle or faciencycle, which is optimally further substituted,
- and B is a carbocycle or beterocycle, which is optionally further substituted,

or a pharmscennically acceptable salt theroof.

At page 17, lines 35-45, the following species is taught. See the compound

## below:

and

At page 20, lines 30-40, the following species is taught. See the compound

depicted below:

Application/Control Number: 10/564,557

Art Unit: 1625

The difference between the prior art compounds and the instantly claimed compounds is the intended use. The instantly claimed compounds are taught to be useful in the treatment of SARS. The prior art compounds are useful in the treatment of the HIV virus.

Cinatl et al. teach a class of antiviral compounds which are useful in inhibiting replication of the SARS virus. At page 1, 1<sup>st</sup> column, Cinatl et al state "Glycyrrhizin was the most active of the antiviral compounds..." As such, it would have been obvious to one of ordinary skill in the art to replace one antiviral compound for another in view of the expectation of similar pharmaceutical activity. Accordingly, the pharmaceutical agents and methods of treating SARS are deemed unpatentable therefrom.

- The Information Disclosure Statements filed January 13, 2006, July 12, 2006, and December 17, 2007 have been considered.
- Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.
- The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300 for regular communications.
- Information regarding the status of an application may be obtained from the
   Patent Application Information Retrieval (PAIR) system. Status information for

Application/Control Number: 10/564,557 Page 7

Art Unit: 1625

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Zinna Northington Davis/ Zinna Northington Davis Primary Examiner Art Unit 1625

Znd 03.31.2008